

SPECIFICATION

COLLAPSIBLE/EXPANDABLE TUBULAR ELECTRODE LEADS

Related Applications

5 This application is related to copending U.S. Patent Application Ser. No. 10/xxx,xxx (attorney docket number 30-7038142001), filed on the same date, and expressly incorporated herein by reference.

Field Of The Invention

The invention relates to the implantation of electrode leads within a patient, 10 and in particular, the implantation of stimulation electrode leads within a patient's spine to treat disorders, such as chronic pain.

Background Of The Invention

It is known to treat chronic pain by electrically stimulating the spinal cord, spinal nerve roots, and other nerve bundles. Although not fully understood, the 15 application of electrical energy to particular regions of the spinal cord induces paresthesia (i.e., a subjective sensation of numbness or tingling) in the afflicted body regions associated with the stimulated spinal regions. This paresthesia effectively masks the transmission of chronic pain sensations from the afflicted body regions to the brain. Since each body region is associated with a particular spinal nerve root, it 20 is important that stimulation be applied at the proper longitudinal position along the spinal cord to provide successful pain management and avoid stimulation of unaffected regions of the body. Also, because nerve fibers extend between the brain and the nerve roots along the same side of the spine as the body regions they

control, it is equally important that stimulation be applied at the proper lateral position of the spinal cord. For example, to treat unilateral pain (i.e., pain sensed only on one side of the body), electrical stimulation is applied to the corresponding side of the spinal cord. To treat bilateral pain (i.e., pain sensed on both sides of the body),
5 electrical stimulation is either applied directly to the midline of the spinal cord or applied to both lateral sides of the spinal cord.

In a typical procedure, one or more stimulation leads are introduced through the patient's back into the epidural space under fluoroscopy. The specific procedure used to implant the stimulation lead will ultimately depend on the type of stimulation
10 lead used. Currently, there are two types of commercially available stimulation leads: a percutaneous lead and a surgical lead.

A percutaneous lead comprises a cylindrical body with ring electrodes, and can be introduced into contact with the affected spinal tissue through a Touhy-like needle, which passes through the skin, between the desired vertebrae, and into the
15 spinal cavity above the dura layer. For unilateral pain, a percutaneous lead is placed on the corresponding lateral side of the spinal cord. For bilateral pain, a percutaneous lead is placed down the midline of the spinal cord, or two percutaneous leads are placed down the respective sides of the midline.

A surgical lead has a paddle on which multiple electrodes are arranged in
20 independent columns, and is introduced into contact with the affected spinal tissue using a surgical procedure, and specifically, a laminectomy, which involves removal of the laminar vertebral tissue to allow both access to the dura layer and positioning of the lead.

After the stimulation lead(s) (whether percutaneous or surgical) are placed at
25 the target area of the spinal cord, the lead(s) are anchored in place, and the proximal

ends of the lead(s), or alternatively lead extensions, are passed through a tunnel leading to a subcutaneous pocket (typically made in the patient's abdominal area) where a neurostimulator is implanted. The lead(s) are connected to the neurostimulator, which is then operated to test the effect of stimulation and adjust the parameters of the stimulation for optimal pain relief. During this procedure, the patient provides verbal feedback regarding the presence of paresthesia over the pain area. Based on this feedback, the lead position(s) may be adjusted and re-anchored if necessary. Any incisions are then closed to fully implant the system.

Various types of stimulation leads (both percutaneous and surgical), as well as stimulation sources and other components, for performing spinal cord stimulation are commercially available from Medtronic, Inc., located in Minneapolis, Minnesota, and Advanced Neuromodulation Systems, Inc., located in Plano, Texas.

The use of surgical leads provides several functional advantages over the use of percutaneous leads. For example, the paddle on a surgical lead has a greater footprint than that of a percutaneous lead. As a result, an implanted surgical lead is less apt to migrate from its optimum position than is an implanted percutaneous lead, thereby providing a more efficacious treatment and minimizing post operative procedures otherwise required to reposition the lead. As another example, the paddle of a surgical lead is insulated on one side. As a result, almost all of the stimulation energy is directed into the targeted neural tissue. The electrodes on the percutaneous leads, however, are entirely circumferentially exposed, so that much of the stimulation energy is directed away from the neural tissue. This ultimately translates into a lack of power efficiency, where percutaneous leads tend to exhaust a stimulator battery supply 25%-50% greater than that exhausted when surgical leads are used. As still another example, the multiple columns of electrodes on a

surgical lead are well suited to address both unilateral and bilateral pain, where electrical energy may be administered using either column independently or administered using both columns.

Although surgical leads are functionally superior to percutaneous leads, there 5 is one major drawback—surgical leads require painful surgery performed by a neurosurgeon, whereas percutaneous leads can be introduced into the epidural space minimally invasively by an anesthesiologist using local anesthesia.

There, thus, remains a need for a minimally invasive means of introducing stimulation leads within the spine of a patient, while preserving the functional 10 advantages of a surgical lead.

Summary Of The Invention

In accordance with a first aspect of the present inventions, a medical lead is provided. The medical lead comprises an electrically insulative tubular membrane having an inner surface and an outer surface, a resilient spring element , and at least 15 one electrode mounted. The spring element is associated with the membrane, e.g., by forming or mounting the spring element onto the membrane, or embedding the spring element into the membrane, and the electrode(s) is associated with the outer surface of the membrane, e.g., by forming or mounting the electrode(s) onto the outer surface, or embedding the springelement into the outer surface. The spring 20 element can be associated with the inner surface or the outer surface of the insulative membrane.

The insulative membrane can be, e.g., continuous, porous, or meshed. The insulative membrane can take on a variety of tubular shapes. For example, the tubular shape can exhibit a circular, rectangular, triangular, or irregular geometry. In

one embodiment, the insulative membrane is allowed to be flaccid and has a relatively low-stiffness, so that it can be made as thin as possible to facilitate collapsing of the medical lead into a low-profile geometry. The spring element is configured to expand the insulative membrane. The spring element can be, e.g., a discrete element or can be formed of a mesh or braid.

5 In one embodiment, the medical lead is configured to inhibit tissue growth. If associated with the inner surface of the insulative membrane, the spring element can be formed of any suitable resilient material, since it is not exposed to tissue. If associated with the outer surface of the insulative membrane, however, the spring 10 element is preferably formed of a material that inhibits tissue growth. For example, in this case, the spring element can be formed of a continuous layer of material. In this manner, the implanted medical lead can be more easily retrieved from the patient's body, if necessary. The medical lead is preferably configured to be collapsed into a compact form for percutaneous delivery into the patient, thereby 15 obviating the need to perform an invasive surgical procedure on the patient. The medical lead, when expanded, can be sized to fit within the epidural space of a patient.

In accordance with a second aspect of the present inventions, another 20 medical lead is provided. The medical lead comprises a resilient tubular structure having a normally non-circular cross-sectional shape (e.g., a rectangle, oval, or crescent), and at least one electrode associated with the tubular structure. The tubular structure may comprise, e.g., a discrete element or can be formed of a mesh or braid. In one embodiment, the medical lead is configured to inhibit tissue growth. The medical lead is preferably configured to be collapsed into a compact form for 25 percutaneous delivery into the patient, thereby obviating the need to perform an

invasive surgical procedure on the patient. The medical lead, when expanded, can be sized to fit within the epidural space of a patient. In this case, the non-cylindrical geometry of the tubular structure allows the tubular structure to conform to the non-cylindrical shaped epidural space, so that, when expanded, painful tissue displacement is minimized.

In accordance with a third aspect of the present inventions, a method of treating a patient with one of the previously described medical leads is provided. The method comprises placing the medical lead into a collapsed state by applying a compressive force to the medical lead, percutaneously delivering the collapsed medical lead into the patient adjacent tissue to be treated, and placing the medical lead into an expanded state by releasing the compressive force. In one preferred method, the medical lead is used to stimulate tissue, such as spinal cord tissue.

Brief Description Of The Drawings

The drawings illustrate the design and utility of preferred embodiment(s) of the invention, in which similar elements are referred to by common reference numerals. In order to better appreciate the advantages and objects of the invention, reference should be made to the accompanying drawings that illustrate the preferred embodiment(s). The drawings, however, depict the embodiment(s) of the invention, and should not be taken as limiting its scope. With this caveat, the embodiment(s) of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Fig. 1 is a plan view of a stimulation lead kit arranged in accordance with a preferred embodiment of the present invention;

Fig. 2 is a cross-sectional view of a stimulation paddle used in the kit of **Fig. 1**, particularly shown in a low-profile collapsed geometry;

Fig. 3 is a cross-sectional view of the stimulation paddle used in the kit of **Fig. 1**, particularly shown in another low-profile collapsed geometry;

5 **Fig. 4** is a cross-sectional view of the stimulation paddle used in the kit of **Fig. 1**, particularly shown in still another low-profile collapsed geometry;

Fig. 5 is a cross-sectional view of a planar stimulation paddle that can be used in the kit of **Fig. 1**, taken along the line 5-5;

10 **Fig. 6** is a cross-sectional view of a curviplanar stimulation paddle that can be used in the kit of **Fig. 1**, taken along the line 6-6;

Fig. 7 is a top view of the stimulation paddle used in the kit of **Fig. 1**;

Fig. 8 is a top view of another stimulation paddle that can be used in the kit of **Fig. 1**;

15 **Fig. 9** is a top view of still another stimulation paddle that can be used in the kit of **Fig. 1**;

Fig. 10 is a top view of yet another stimulation paddle that can be used in the kit of **Fig. 1**;

Fig. 11 is a top view of yet another stimulation paddle that can be used in the kit of **Fig. 1**;

20 **Fig. 12** is a top view of yet another stimulation paddle that can be used in the kit of **Fig. 1**;

Fig. 13 is a top view of yet another stimulation paddle that can be used in the kit of **Fig. 1**;

25 **Fig. 14** is a perspective view of a stimulation tube that can be used in the kit of **Fig. 1**;

Fig. 15 is a cross-sectional view of the stimulation tube of **Fig. 14**, particularly showing its cross-sectional rectangle shape when placed in an expanded geometry;

Fig. 16 is a cross-sectional view of an alternative stimulation tube, particularly showing its cross-sectional oval shape when placed in an expanded geometry;

5 **Fig. 17** is a cross-sectional view of another alternative stimulation tube, particularly showing its cross-sectional crescent shape when placed in an expanded geometry;

Fig. 18 is a cross-sectional view of the stimulation tube of **Fig. 14**, particularly shown in a low-profile collapsed geometry;

10 **Fig. 19** is a perspective view of another stimulation tube that can be used in the kit of **Fig. 1**;

Fig. 20 is a cross-sectional view of the stimulation tube of **Fig. 19**, taken along the line 20-20; and

15 **Figs. 21A-21D** are various views illustrating the installation of the kit of **Fig. 1** into a patient's spine.

Detailed Description Of The Preferred Embodiments

Referring now to **Fig. 1**, a spinal cord stimulation lead kit 100 arranged in accordance with one preferred embodiment of the present invention is shown. In its simplest form, the stimulation kit 100 generally comprises a stimulation lead 102, which is configured to be percutaneously delivered and implanted into the epidural space of a patient's spine, an implantable electrical stimulation source 104 configured for delivering stimulation energy to the stimulation lead 102, and an optional extension lead 106 configured for connecting the stimulation lead 102 to the remotely implanted stimulation source 104.

It should be noted that although the kit 100 illustrated in **Fig. 1** is described herein as being used in spinal cord stimulation (SCS) for the treatment of chronic pain, the kit 100, or a modification of the kit 100, can be used in an SCS procedure to treat other ailments, or can be used in other applications other than SCS procedures, 5 such as peripheral nervous system stimulation, sacral root stimulation, and brain tissue stimulation, including cortical and deep brain stimulation. In the latter case, the stimulation lead 102 can be delivered through a miniature cranial burr hole into the brain tissue.

The stimulation lead 102 comprises an elongated sheath body 108 having a 10 proximal end 110 and a distal end 112. The sheath body 108 is composed of a suitably flexible material (such as polyurethane, silicone, etc.), which may either be resilient or non-resilient, and may be formed via an extrusion process or by any other suitable means. In the illustrated embodiment, the sheath body 108 is cylindrically-shaped and sized to fit through a Touhy-like needle (not shown). In this case, the 15 diameter of the sheath body 108 is preferably less than 5 mm to allow it to be percutaneously introduced through a needle. More preferably, the diameter of the sheath body 108 is within the range of 1 mm to 3 mm, so that the stimulation lead 102, along with the secondary stimulation leads 104 described below, can comfortably fit within the epidural space of the patient. The sheath body 108 may 20 have other cross-sectional geometries, such as oval, rectangular, triangular, etc. If rectangular, the width of the stimulation lead 102 can be up to 5 mm, since the width of an epidural space is greater than its height. The sheath body 108 may have an optional lumen (not shown) for receiving an obturator (not shown) that axially stiffens the sheath body 108 to facilitate percutaneous introduction of the stimulation lead

102 within the epidural space of the patient's spine, as will be described in further detail below.

The stimulation lead 102 further comprises a plurality of terminals 114 (in this case, four) mounted on the proximal end 110 of the sheath body 108. The terminals 5 114 are formed of ring-shaped elements composed of a suitable biocompatible metallic material, such as platinum, platinum/iridium, stainless steel, gold, or combinations or alloys of these materials, and can be mounted to the sheath body 108 in an interference fit arrangement.

The stimulation lead 102 further comprises a stimulation paddle 116 suitably 10 mounted to the distal end 112 of the sheath body 108. In this embodiment, the stimulation paddle 116 is laterally centered on the sheath body 108, but as will be discussed below, the electrode paddle 116 can alternatively be laterally offset from the sheath body 108. As will be described in further detail below, the stimulation paddle 116 is configured to be placed into a compact, low-profile geometry by, e.g., 15 rolling (see **Fig. 2**) or folding (see **Figs. 3 and 4**) the paddle 116, and maintained in this low-profile geometry by applying a radial compressive force to the paddle 116, such as the force that would be applied by the lumen of a delivery device. Upon release of the radial compressive force, such as when the paddle 116 exits the delivery device, the paddle 116 springs open into its normally expanded geometry. 20 In the illustrated embodiment, the paddle 116 expands into a planar geometry, as illustrated in **Fig. 5**. Alternatively, the paddle 116 can expand into a curviplanar geometry (i.e., a plane existing in three-dimensional space, e.g., a plane having an arcuate, curved, or undulating shape), as illustrated in **Fig. 6**.

Referring further to **Fig. 7**, the stimulation paddle 116 comprises a paddle-shaped membrane 118 having a surface 124, an array of electrodes 120 mounted on 25

the membrane surface 124, and a skeletal spring element 122 mounted on the membrane surface 124 between the electrodes 120. Alternatively, the electrodes 120 and skeletal spring element 122 can be respectively formed onto oppositely disposed surfaces of the membrane 118, so that the routing of the spring element 122 can be accomplished independently of the electrodes 120. To prevent or inhibit tissue growth after the stimulation lead 102 is implanted, the surface of the stimulation paddle 116 is preferably smooth and free of discontinuities that would otherwise be found in tissue growth exhibiting surfaces, such as mesh or braided material. In this manner, the implanted lead 102 can be more easily and percutaneously removed if necessary.

The electrodes 120 can be formed onto the membrane 118 using known deposition processes, such as sputtering, vapor deposition, ion beam deposition, electroplating over a deposited seed layer, or a combination of these processes. Alternatively, the electrodes 120 can be formed onto the membrane 118 as a thin sheet or foil of electrically conductive metal. Or, the electrodes 120 can be discrete elements that are embedded into the membrane 118, such that they lie flush with the surface 124 of the membrane 118. The electrodes 120 can be composed of the same electrically conductive and biocompatible material as the terminals 114, e.g., platinum, platinum/iridium, stainless steel, gold, or combinations or alloys of these materials. In the embodiment illustrated in Fig. 7, the electrodes 120 are arranged in a single column of four elements extending along the midline of the membrane 118. As will be described in further detail below, the electrodes 120 can have other configurations. In the illustrated embodiment, the electrodes 120 are circular, but can be formed as other geometric shapes, such as rectangular or ellipsoidal.

The stimulation lead 102 further comprises a plurality of conductors (not shown) extending through the sheath body 108 and membrane 118 and connecting each electrode 120 with a respective terminal 114. The conductors 122 are composed of a suitably electrically conductive material that exhibits the desired 5 mechanical properties of low resistance, corrosion resistance, flexibility, and strength.

In the illustrated embodiment, the membrane 118 is composed of a continuous layer of material, although alternatively, the membrane 118 may be porous, meshed, or braided. Whether continuous or not, the material from which the 10 membrane 118 is composed is relatively thin (e.g., 0.1 mm to 2 mm, although 1 mm or less is most preferred) and has a relatively low-stiffness. Exemplary materials are low-stiffness silicone, expanded polytetrafluoroethylene (ePTFE), or urethane. Due to these properties, the stimulation paddle 116 can be more easily collapsed into a low-profile geometry. For example, the stimulation paddle 116 can be rolled (see 15 **Fig. 2**), or folded along one or more fold lines (see **Figs. 3 and 4**). Although these properties allow the stimulation paddle 116 to be more easily collapsed into a low-profile geometry, thereby facilitating percutaneous delivery of the lead 102, these same properties also cause the membrane 118 to be too flaccid to easily spring open from the low-profile geometry. Radio-opaque markers (not shown) may 20 optionally be provided on the membrane 118, so that the stimulation paddle 116 may be more easily navigated and placed into the epidural space of the patient under fluoroscopy.

The skeletal spring element 122, however, advantageously provides this necessary spring force. In particular, the spring element 122 is composed of a 25 relatively high-stiffness and resilient material, such as stainless steel, a metallic and

polymer material, or a high-stiffness urethane or silicone, that is shaped into a normally planar (curviplanar) geometry. In alternative embodiments, the spring element 122 may be composed of a shape memory material, such as nitinol, so that it assumes a planar (or curviplanar) geometry in the presence of a defined 5 temperature, such as, e.g., body temperature. Thus, it can be appreciated that the normally planar (or curviplanar) geometry of the spring element 122 will cause the stimulation paddle 116 to likewise assume a planar (curviplanar) geometry in the absence of an external force (in particular, a compressive force). In the illustrated embodiment, the spring element 122 is formed of a thin layer of material that is 10 laminated onto the membrane 118. In effect, the spring element 122 has a two-dimensional geometry in that it has a length and a width, but a minimal thickness. As a result, protrusions from the membrane 118 are avoided, thereby allowing the stimulation paddle 116 to be placed into a lower collapsed profile. Alternatively, the spring element 122 can be made from wire, which is cylindrical in nature, and thus, 15 can be said to have a three-dimensional geometry. Whether formed from a layer of material or a wire, the spring element 122 may alternatively be embedded into the membrane 118, so that the surface of the spring element 122 is flush with the surface 124 of the membrane 118.

As can be seen in Fig. 7, the spring element 122 is formed of a single linear 20 element that longitudinally extends along the membrane 118 in a meandering fashion between the electrodes 120. In this case, the laterally extending curves of the meandering spring element 122 act as cross-supports that provide the necessary spring force to urge the stimulation paddle 116 from its low-profile collapsed geometry into its expanded geometry. Notably, the end of the spring element 122 is

beaded to prevent inadvertent perforation of the membrane 118 when the stimulation paddle 116 is mechanically stressed.

The spring element 122 can have other geometries. For example, **Fig. 8** illustrates a stimulation paddle 126 that comprises a skeletal spring element 132 that 5 includes a main spring segment 134 that is similar to the spring element 122 illustrated in **Fig. 7**, and additional secondary spring segments 135 that extend longitudinally from the apexes of the main spring segment curves. The longitudinally extending secondary spring segments 135 provide additional axial stiffness to the stimulation paddle 126, thereby facilitating axial movement (i.e., the pushability) of 10 the expanded stimulation paddle 126 by minimizing axial buckling of the membrane 118. To prevent inadvertent perforation of the insulative membrane 118, the distal ends of the secondary spring segments 135 are beaded.

As another example, **Fig. 9** illustrates a stimulation paddle 136 having a skeletal spring element 122 that includes a main spring segment 144 that extends 15 longitudinally along the centerline of the membrane 118, and a plurality of lateral spring segments 145 that branch off of the main spring segment 144 between the electrodes 120. As can be seen in **Fig. 9**, the electrodes 120 are arranged as two columns of four elements each extending down the lateral sides of the membrane 118. Besides providing a structure from which the lateral spring segments 144 are 20 supported, the main spring segment 144 provides axial stiffness to the stimulation paddle 146, thereby facilitating axial movement (i.e., the pushability) of the expanded stimulation paddle 146 by minimizing axial buckling of the membrane 118. To this end, the main spring segment 144 is somewhat wider than the lateral spring segments 145. The lateral spring segments 145 act as cross-members that urge the 25 membrane 118 into its normally expanded state, thereby providing the spring force

that transforms the collapsed membrane 118 into the expanded geometry in the absence of a compressive force.

Fig. 10 illustrates a stimulation paddle 146 that comprises a skeletal spring element 152, which is similar to the previously described spring element 152, with 5 the exception that it comprises lateral staggered spring segments 155 that are not linear, but are rather formed into two dimensional shapes—in this case a leaf shape. This increased size of the lateral spring segments 155 provides increased lateral 10 spring force to the stimulation paddle 146. In this case, the number of lateral segments 155 are decreased, and the electrodes 120 are arranged into two columns of two elements each.

Fig. 11 illustrates a stimulation paddle 156 that comprises a skeletal spring element 162 with a plurality of diamond-shaped elements 164 longitudinally extending down the midline of the membrane 118 and a plurality of innerconnecting segments 165 between the respective diamond-shaped elements 164. The 15 electrodes 120 are arranged in a single column of four electrodes 120 that extend down the midline of the membrane 118 between the respective diamond-shaped elements 164. The interconnecting segments 165 are curved in alternating left and right lateral directions in order to accommodate the centered electrodes 120.

Fig. 12 illustrates a stimulation paddle 166 that comprises a skeletal spring 20 element 172 with a trunk segment 173, two main spring segments 174 that longitudinally extend from the trunk segment 173 along the left and right lateral sides of the membrane 118, and lateral spring segments 175 that branch off of the main spring segments 174 towards the midline of the membrane 118. Like the main spring segment 144 of the stimulation paddle 136 illustrated in Fig. 9, the main 25 spring segments 174 provide axial rigidity to the stimulation paddle 166, while

providing a structure supporting the lateral spring segments 175. Like the lateral spring segments 175 of the stimulation paddle 166 illustrated in **Fig. 11**, the lateral spring segments 175 act as cross members that facilitate transformation of the stimulation paddle 166 from its collapsed geometry into its expanded geometry. To 5 prevent inadvertent perforation of the insulative membrane 118, the distal ends of the main spring segments 174 and secondary spring segments 175 are beaded. The electrodes 120 are arranged in a single column of four electrodes 120 extending down the midline of the membrane 118 between the respective secondary spring segments 175.

10 **Fig. 13** illustrates a stimulation paddle 176 that comprises a membrane 118 that is laterally offset from the distal end 112 of the elongated sheath 108, and a skeletal spring element 182 with a main spring segment 184 that longitudinally extends along the membrane 118 and lateral spring segments 185 that laterally branch off from the main spring segment 184 towards the other lateral side of the 15 membrane 118. The main spring segment 184 and lateral spring segments 185 function in the same manner as the main spring segment 144 and lateral spring segments 145 of the spring element 132 illustrated in **Fig. 9**. To prevent inadvertent perforation of the insulative membrane 118, the distal ends of the secondary spring segments 185 are beaded. The electrodes 120 are arranged in a single column of 20 four elements that longitudinally extend down the midline of the membrane 118 between the lateral spring segments 185.

Although all of the stimulation paddles illustrated in **Figs. 7-13** have single spring elements, stimulation paddles with multiple spring elements can also be provided. In addition, tubular designs, which are, in effect, stimulation paddles that

are wrapped around onto themselves, can be formed, in order to provide a more stable and snug engagement within the epidural space.

In particular, **Figs. 14 and 15** illustrate a stimulation lead 202 that can alternatively be used in the kit 100 of **Fig. 1**. The stimulation lead 202 is similar to 5 the stimulation 102 described above, with the exception that it comprises a stimulation tube 216, rather than a stimulation paddle. The stimulation tube 216 comprises a tubular, and specifically, rectangular cross-sectional shaped, membrane 218 having an outer surface 224, an array of electrodes 220 mounted on the outer surface 224, and skeletal spring elements 222 mounted on the outer surface 224 10 between the electrodes 220. Alternatively, the electrodes 220 can be mounted on the outer surface 224, and the spring elements 222 can be mounted on an inner surface of the tubular membrane 218, so that the routing of the spring element 222 can be accomplished independently of the electrodes 220. To prevent or inhibit tissue growth after the stimulation lead 202 is implanted, the outer surface 224 of the 15 stimulation tube 216 is preferably smooth and free of discontinuities that would otherwise be found in tissue growth exhibiting surfaces, such as mesh or braided material. In this manner, the implanted lead 202 can be more easily and percutaneously removed if necessary.

The electrodes 220 can be composed of the same material, shaped, and 20 formed onto the membrane 218 in the same manner as the electrodes 120. In the embodiment illustrated in **Fig. 14**, the electrodes 220 are arranged in a single column of four elements longitudinally extending along one side of the membrane 218. Like the paddle membrane 118, the tubular membrane 218 is formed of a relatively thin (e.g., 0.1 mm to 2 mm, although 1 mm or less is most preferred), and 25 is composed of a relatively low-stiffness material, such that it can be collapsed into a

low-profile geometry, as shown in **Fig. 18**. Also, like the paddle membrane 118, the tubular membrane 218, by itself, is too flaccid to easily spring open from the low-profile geometry. Again, the skeletal spring elements 222 provide this necessary spring force, so that the stimulation tube 216 can expand outward in the absence of 5 an external compressive force. The spring elements 222 can be composed of the same material and can be formed onto the membrane 218 in the same manner as the previously described spring element 122. In the embodiment illustrated in **Fig. 14**, each of the spring elements 222 extends around the circumference of the tubular membrane 218 in a meandering fashion. Of course, other spring element 10 configurations can be used.

Although the membrane 218 is illustrated as having a normally expanded rectangular geometry, as best shown in **Fig. 15**, the membrane 218 can alternatively have other non-cylindrical tube-like shapes. For example, **Fig. 16** illustrates an alternative tubular membrane 216' that has an oval cross-sectional shape, and **Fig. 15** **17** illustrates another tubular membrane 216" that has a crescent cross-sectional shape. The crescent-shaped tubular membrane 216" lends itself particular well to spinal cord stimulation, since the spinal cord can be comfortably seated within a concave region 216 of the tubular membrane 216".

Figs. 19 and 20 illustrate another stimulation tube 236 that is similar to the 20 stimulation tube 216, with the exception that, rather than having discrete spring elements, it comprises a resilient spring element 242 formed of a mesh or braid that may be composed of the same base material as the previously described spring elements. The tube 236 also has an oval cross-sectional shape, rather than a rectangular cross-sectional shape. The spring element 242 is formed on an inner 25 surface of the tubular membrane 218, so that the mesh or braid material is not in

contact with tissue, and therefore does not inhibit tissue growth. Like the spring element 222, the spring element 242 serves to urge the tubular membrane 218 from a low-profile collapsed geometry to an expanded geometry. As shown in Fig. 19, the distal and proximal ends of the stimulation tube 236 are tapered to allow for a safer deployment and, if necessary, retrieval of the device.

Referring back to Fig. 1, the implantable stimulation source 104 is designed to deliver electrical pulses to the stimulation lead 102 in accordance with programmed parameters. In the preferred embodiment, the stimulation source 104 is programmed to output electrical pulses having amplitudes varying from 0.1 to 20 volts, pulse widths varying from 0.02 to 1.5 milliseconds, and repetition rates varying from 2 to 2500 Hertz. In the illustrated embodiment, the stimulation source 104 takes the form of a totally self-contained generator, which once implanted, may be activated and controlled by an outside telemetry source, e.g., a small magnet. In this case, the pulse generator has an internal power source that limits the life of the pulse generator to a few years, and after the power source is expended, the pulse generator must be replaced. Generally, these types of stimulation sources 106 may be implanted within the chest or abdominal region beneath the skin of the patient.

Alternatively, the implantable stimulation source 104 may take the form of a passive receiver that receives radio frequency (RF) signals from an external transmitter worn by the patient. In this scenario, the life of the stimulation source 104 is virtually unlimited, since the stimulation signals originate from the external transmitter. Like the self-contained generators, the receivers of these types of stimulation sources 106 can be implanted within the chest or abdominal region beneath the skin of the patient. The receivers may also be suitable for implantation behind the ear of the patient, in which case, the external transmitter may be worn on

the ear of the patient in a manner similar to that of a hearing aid. Stimulation sources, such as those just described, are commercially available from Advanced Neuromodulation Systems, Inc., located in Plano, Texas, and Medtronic, Inc., located in Minneapolis, Minnesota.

5 The optional extension lead 106 comprises an elongated sheath body 109 having a proximal end 111 and a distal end 113, much like the sheath body 108 of the stimulation lead 102, a proximal connector 115 coupled to the proximal end 113 of the sheath body 109, a distal connector 117 coupled to the distal end 111 of the sheath body 109, and a plurality of electrical conductors (not shown) extending 10 through the sheath body 109 between the proximal and distal connectors 115/117. The length of the extension lead 102 is sufficient to extend from the spine of the patient, where the proximal end of the implanted stimulation lead 102 protrudes from to the implantation site of the stimulation source 104—typically somewhere in the chest or abdominal region. The proximal connector 115 is configured to be coupled 15 with to the stimulation source 104, and the distal connector 117 is configured to mate with the proximal end of the stimulation lead 102.

Having described the stimulation lead kit 100, its installation and use in treating chronic pain will now be described with reference to **Figs. 21A-21D**. After the patient has been prepared (which may involve testing the efficacy of spinal cord 20 stimulation on the patient, and, once determining that the patient can be effectively treated with spinal cord stimulation, identifying and marking the appropriate vertebral intervals on the patient's skin and applying a local anesthetic to this region), a needle 10, such as, e.g., a Touhy needle, is inserted through the patient's skin 12 between the desired vertebrae 14, and into the epidural space 16 within the spine at a 25 position inferior to target stimulation site 18 (**Fig. 21A**). In the illustrated method, the

Touhy needle 10 will serve as the primary delivery mechanism for the stimulation lead 102. Alternatively, if an optional introducer (not shown) is used, a guide wire (not shown) is introduced through the needle 10 and advanced to or near the target stimulation site 18. The needle 10 is removed, the introducer is then introduced over 5 the guide wire and advanced to the target stimulation site 18, and the guide wire is then withdrawn. In this case, the introducer will serve as the primary delivery mechanism for the stimulation lead 102.

After the deliver mechanism is in place, the stimulation lead 102, with the stimulation paddle 116 collapsed into a low-profile geometry (see Figs. 2-4), is then 10 inserted through the needle or the introducer (whichever is in place), and positioned in the epidural space 16 at the target stimulation site 18 (Figs. 21B and 21C). The stimulation tubes 216/236 can be inserted through the needle or the introducer in the same manner. If the stimulation lead 102 has an obturator lumen, an obturator can be used to provide additional axial stiffness and to facilitate control. Once the 15 compressive radial force applied by the delivery device is released, the stimulation paddle 116 expands into its normally planar geometry, with the electrodes 120 facing the dural layer 20 and spanning the midline of the spinal cord 22 (Fig. 21D). If stimulation tubes 216/236 are used, their two-dimensional expansion will provide a more secure engagement within the epidural space. Notably, the use of non- 20 cylindrical stimulation tubes, when expanded, conform better to the non-cylindrical epidural space 16, thereby minmizing painful tissue displacement.

Next, the needle 10 or introducer is removed, and the proximal end of the stimulation lead 102 is connected to a tester (not shown), which is then operated in a standard manner to confirm proper location of the stimulation lead 102 and to adjust 25 the stimulation parameters for optimal pain relief. Once this optimization process

has been completed, the tester is disconnected from the stimulation lead 102, which

is then anchored in place using standard lead anchors (not shown). In the case of

stimulation tubes 216/236, anchors may not be necessary, since they self-anchor

themselves within the epidural space when expanded. Next, the stimulation lead

5 102 is coupled to the stimulation source 104 and implantation is completed (not shown). In particular, a subcutaneous pocket is created in the patient's abdominal area for implantation of the stimulation source 104, and a tunnel is subcutaneously formed between the spine region and the subcutaneous pocket. The optional lead extension 106 is passed through the tunnel, after which the adapter 154 of the

10 extension 106 is connected to the proximal end of the stimulation leads 102 and the connector 156 of the lead extension 106 is connected to the stimulation source 104. The stimulation source 104 is programmed and tested, and then placed within the subcutaneous pocket, after which all incisions are closed to effect implantation of the stimulation lead 102 and stimulation source 104. The stimulation source 104 can

15 then be operated to convey stimulation energy from the stimulation source 104 to the electrodes 120 of the stimulation lead 102, where it is, in turn, conveyed into the neural tissue for pain relief.

It can be appreciated that the relatively large footprint made by the stimulation

lead 102, much like a prior art surgical lead, provides a more stable platform for the

20 electrodes 120. Also, like a prior art surgical lead, the electrodes 120 face in a single

direction, thereby focusing the stimulation energy into the affected neural tissue

where it is needed. Unlike a surgical lead, however, the stimulation lead 102 can be

percutaneously delivered into the patient's spine in a minimally invasive and

relatively pain-free manner, without requiring extensive patient recovery.

Although particular embodiments of the present invention have been shown and described, it should be understood that the above discussion is not intended to limit the present invention to these embodiments. It will be obvious to those skilled in the art that various changes and modifications may be made without departing from 5 the spirit and scope of the present invention. Thus, the present invention is intended to cover alternatives, modifications, and equivalents that may fall within the spirit and scope of the present invention as defined by the claims.